

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed September 27, 2010. Claims 24-40 and 47-49 were pending and rejected in view of cited art. Claims 26 and 39 are canceled, while claims 24, 29, 31, 38, and 47 are amended. Claims 24, 25, 27-38, 40 and 47-49 are now pending in view of the above amendments, with claims 24 and 47 being the independent claims. Support for the amendments to the claims can be found, at least, in the originally filed claims, FIG. 2B, and the specification paragraphs [0043], [0044], [0050] and [0051].

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH AND SECOND PARAGRAPH

The Office Action rejected claims 24-40 and 47-49 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and rejected claims 24-40 and 47-49 under 35 U.S.C. § 112, second paragraph, as being indefinite. In response, independent claims 24 and 47 have been amended to clarify the claimed invention. In view of the amendments to the claims, Applicant respectfully requests withdrawal of the rejection under Section 112.

C. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. §§102(E) AND 103(A)

As presented herein for reconsideration (see independent claim 24, as exemplary), claimed in independent claims 24 and 47 is "an apparatus for sealing a puncture tract disposed

within tissue.” The apparatus includes, for example in independent claim 1, a housing, a manifold, a shaft, and a plurality of needles. The manifold includes “an inlet port and a central opening, the manifold slidably engaging with the housing and being configured to receive a closure agent” of the apparatus. The “shaft [is] disposed through the housing and the central opening” with “an expandable member disposed from a distal end of the shaft” and “being configured to be disposed within the puncture tract to stabilize the tissue.” The “needles [of the apparatus are] mounted to the manifold” with the “needles being slidable with the manifold to extend from the housing.” These needles are “configured to penetrate tissue surrounding the puncture tract to deliver a closure agent from the manifold into the tissue to thereby seal the puncture tract.”¹

The Office Action rejected claims 24-26, 28-32, 34, 35, 38-40, and 47-49 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 7,291,129 (*Li*). Claims 24-32, 34, 35, 38-40, and 47-49 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,692,466 (*Chow*). The Office Action also rejected (i) claim 27 under 35 U.S.C. § 103(a) as being unpatentable over *Li* as applied to claim 24, and further in view of U.S. Patent No. 6,835,193 (*Epstein*), (ii) claim 33 under 35 U.S.C. § 103(a) as being unpatentable over *Li* as applied to claim 24, and further in view of U.S. Patent No. 7,008,439 (*Janzen*), (iii) claims 36 and 37 under 35 U.S.C. § 103(a) as being unpatentable over *Li* as applied to claim 24 and 33, and further in view of U.S. Publication No. 2002/0143291 (*Slater*), and (iv) claims 36 and 37 under 35 U.S.C. § 103(a) as being unpatentable over *Chow* as applied to claims 24 and 33, and further in view of *Slater*.² Applicant respectfully traverses and respectfully submits that the independent claims as presented for reconsideration are not anticipated nor made obvious by *Li* and/or *Chow* either singly or in combination with any other reference of record.³

¹ Independent claim 47 is similar. Claim 47 differs from claim 24 by adding the further limitation of “a housing having a base with a lumen . . . the shaft including a stop configured to cooperate with the base . . . the stop being configured to limit longitudinal movement of the manifold relative to the expandable member.”

² Since the references relied upon in the Office action qualify as “prior” art, if at all, under 35 U.S.C. 102(a)/(e), applicants reserve the right to challenge the status of any reference as qualifying “prior” art. Accordingly, any statement or comment herein to any of the references relied upon in the Office action is made merely for purposes of argument, and assumes *arguendo* that such reference or references are proper qualifying prior art.

³ Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

Turning firstly to *Li*, it discloses an "apparatus and methods for treating female urinary incontinence" with the apparatus including an "injection port 27 that is coupled to needles 21" (col. 1, ll. 13-14 and col. 4, ll. 43-44). Those needles "are affixed in block 32" which is in turn "connected to rod 30, so that reciprocation of actuator 28 causes deployment or retraction of needles 21" (col. 4, ll. 52-54). The needles are also "in fluid communication with injection port 27 via tubing 31" (col. 4, ln. 48). The rod 30 and the actuator 28, with associated slide block 29, move the needles rather than injection port 27 and the tubing 31. Thus, no mention is made in *Li* of the slide block 29, with associated actuator 28, receiving any closure agent, which is delivered to the needles, or that the injection port 27 moves to deploy the needles. Furthermore, *Li* makes no mention of the distal region 14 of the shaft 11 sliding, whether relative to the handle 15, the injection port 27, or the slide block 29, and the distal region 14 or the inflation tube 23 does not pass through the injection port 27 or the tubing 31.

Turning secondly to *Chow*, it discloses a catheter assembly 10 having "an elongated catheter body 12" and includes "a guidewire lumen 18" and a "balloon 20 . . . in fluid communication with an inflation lumen 22" (col. 4, ll. 3-5 and 7-9). The catheter assembly 10 also includes "a therapeutic substance delivery assembly 38 for injecting a therapeutic substance" (col. 4, ll. 62-64). "In one embodiment, delivery assembly 38 includes a needle 46 disposed within a hollow delivery lumen 40" with "[a]ccess to the proximal end of delivery lumen 40 for insertion of needle 46" being provided "through a hub 51" (col. 4, ln. 64 to col. 5, ll. 3-5). "The central lumen of needle 46 connects dispensing port 53 [at the distal end of needle 46] with therapeutic substance port 59, which is configured to be coupled to various substance dispensing means . . . , for example, a syringe or fluid pump" (col. 5, ll. 38-42).

The port 59, identified in the Office Action as the manifold, does not receive any portion of the inflation lumen 22 associated with the balloon 20. Furthermore, the hub 51, needle lock 55, and adjustment knob 57, do not receive any portion of the inflation lumen 22 associated with the balloon 20. Thus, *Chow* neither teaches nor suggests the inclusion of "a shaft slidably disposed through the housing and the central opening of the manifold and having an expandable member disposed from a distal end of the shaft" as recited in independent claims 24 and 47.

Thus, *Li* and/or *Chow* clearly do not anticipate or make obvious Applicant's claimed apparatus (e.g., see claims 24 and 47) which requires, *inter alia*, "a manifold having an inlet port and a central opening, the manifold slidably engaging with the housing and being configured to receive a closure agent", with "a shaft slidably disposed through the housing [or the lumen of the

housing as recited in independent claim 47] *and the central opening of the manifold*" and "the shaft having an expandable member disposed from a distal end of the shaft" and "*a plurality of needles mounted to the manifold, the plurality of needles being slidable with the manifold to extend from the housing*" (Claims 24 and 47, emphasis added)

Accordingly, for at least the reasons noted, independent claims 24 and 47 and the claims depending therefrom⁴ are neither anticipated nor made obvious by *Li* and/or *Chow*, either singly or in combination with any other prior art of record⁵, and thus reconsideration and withdrawal of the rejection is respectfully requested.

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner

⁴ Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims 24, 25, 27-40, 48, and 49 but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims 24, 25, 27-40, 48, and 49.

⁵ *Epstein*, *Janzen*, and *Slater* were cited as secondary references. *Epstein* was cited for the proposition that it discloses "an apparatus comprising a stop (15 and 14) to limit translation of a needle into body tissue" (Office Action, p. 5). *Janzen* was cited for the proposition that it discloses "at least one balloon coupled to the needle" (Office Action, p. 6). *Slater* was cited for the proposition that it discloses "a radiopaque marker (58) disposed adjacent to the distal tip of a surgical insertion tool (26)" (Office Action, p. 7). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Li* and/or *Chow*. Thus, even assuming *arguendo* that any of the references to *Epstein*, *Janzen*, and *Slater* are properly combinable with *Li* and/or *Chow*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Li* and/or *Chow*.

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finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 26th day of January, 2010.

Respectfully submitted,

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